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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,544	07/18/2005	Jerome Asius	A100001U	6859

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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,544	ASIUS ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/19/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34 and 36-69* is/are pending in the application.

4a) Of the above claim(s) *34,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

This Office Action is in response to the amendment filed January 19, 2010. **Claims 34 and 36-69 are pending**. **Claims 38-69 are under consideration in the instant office action.** Claims 34 and 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 1-33 and 35 are cancelled. Applicants newly added claims 38-69. Applicants' amendment has necessitated a new ground of rejections. Accordingly, this Action is FINAL.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34 and 36-37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Moot Rejections/Objections

All rejections and/or objections of claims 1-33 and 35 cited in the previous office action mailed on October 05, 2009 are moot, because said claim(s) has/have been cancelled.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

All cited prior art has previously been cited of record.

Claims 38-46, 49-51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) in view of Janas et al. (US Patent No. 6451059).

Applicant Claims

Applicants claim a resorbable implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid, wherein said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months and have a size of from 10 to 80 μm, said ceramic compound is tricalcium phosphate (βTCP) and has a specific surface area of from 0.5 m^2/g to 100 m^2/g, and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties. The dependent claims thereof recite sizes of microparticles, contents of fluids, surface area of the ceramic compound, durations of biological properties of the implant, amounts of vector fluid, and forms of implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Hubbard et al. teach a permanent, biocompatible material for soft tissue augmentation (see abstract). **The biocompatible material comprises a matrix of smooth, round, finely divided, substantially spherical particles of a biocompatible ceramic material, close to or in contact with each other, which provide a scaffold or lattice for autogenous, three dimensional, randomly oriented, non-scar soft tissue growth at the augmentation site** (see abstract). **The augmentation material can be homogeneously suspended in a biocompatible, resorbable lubricious gel carrier comprising a polysaccharide** (see abstract). Hubbard et al. teach that the augmentation material comprises smooth rounded, substantially spherical, **particles of a ceramic material** (column 5, lines 11-13). Hubbard et al. also teach that the particles must be sufficiently small so as to avoid aggregation and clogging of the syringe

when being injected (column 5, lines 27-29). **A typical range for injection is from about 35 to 150 microns, preferably in a narrow particle size range extending not more than about 35 microns, and more preferably extending not more than about 10 to 30 microns, and most preferably having substantially equivalent particle sizes** (column 5, lines 31-34). Hubbard et al. teach that useful ceramic materials include **tricalcium phosphate** (column 7, line 45). Hubbard et al. also teach the particulate ceramic material can be suspended in a biocompatible, resorbable lubricant, such as a polysaccharide gel to improve the delivery of the augmentation material by injection to the tissue site where augmentation is desired (column 10, lines 13-16). **Suitable polysaccharides include hyaluronic acid, hyaluronic acid and xanthan** etc., (column 10, lines 21 and 30). Preferred polysaccharides for use in the present invention include, for example, **agar methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, microcrystalline cellulose, oxidized cellulose, chitin, chitosan, alginic acid, sodium alginate, and xanthan gum** (column 10, lines 35-39). Hubbard et al. also teach in the tissue augmentation material and method of the present invention, other polysaccharides can also be included or used separately such as **xanthan gum** (column 12, lines 38-39 and 44). Hubbard et al. also teach **the augmentation material can easily be injected through an 18 gauge or smaller syringe intradermally or subcutaneously** (column 14, lines 5-7). Hubbard et al. also teach a substantially dehydrated biocompatible composition, comprising a biocompatible, resorbable, medium for suspending a biomaterial, the suspending medium comprising a dehydrated polysaccharide gel for maintaining the biomaterial suspended in the implant composition, the dehydrated composition being directly implantable into a living body (see claim 42). **The polysaccharide gel comprises a cellulose polysaccharide selected from the group**

consisting of sodium carboxymethylcellulose, agar methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, microcrystalline cellulose and oxidized cellulose (see claim 46). The biomaterial is a ceramic (claim 49). The ceramic particles are selected from the group consisting of calcium hydroxyapatite particles, tetracalcium phosphate particles, calcium pyrophosphate particles, **tricalcium phosphate particles**, octacalcium phosphate particles, calcium fluorapatite particles, calcium carbonate apatite particles and mixtures thereof (see claim 53). With regard to the recitations of the duration at which the implant material would be biodegradable in instant claims 38 and 45-46 since the product taught by Hubbard et al. is substantially similar to the instantly claimed product, the product of Hubbard et al. is necessarily expected to take similar durations to degrade under physiological conditions.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Hubbard et al. do not explicitly teach the surface area. This deficiency is cured by the teachings of Janas et al.

Janas et al. teach a hard tissue scaffold comprising a resorbable ceramic (see abstract). Janas et al. teach in illustrative example particles of ceramic tricalcium phosphate, $Ca_3(PO_4)_2$, with a BET surface area of 1.708 m^2/gm, were milled in water containing a sodium silicate surfactant to create dispersion.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the **biocompatible** material of Hubbard et al. via the incorporation of ceramic particles with surface areas as specified in the claims, because Janas et

al. teach the incorporation of particles of ceramic tricalcium phosphate with a BET surface area of 1.708 m^2/gm. The skilled artisan would have been motivated to optimize the surface area of the particles because in such injectable implants particle sizes and surface areas control whether the biocompatible material will be injectable using syringes. Additionally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Janas et al., because both references teach similar biocompatible materials that can be used for tissue augmentation.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 38 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) in view of Janas et al. (US Patent No. 6451059) and Draenert (US Patent No. 4373217).

Applicant Claims

The claimed subject matters of instant claim 38 are set forth above. Instant claim 47 recites the implant according to claim 38 wherein the microparticles are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%. Instant claim 48 recites the implant according to claim 38 wherein the microparticles are present in the vector fluid in a weight/volume proportion from 2% to 12%.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al., and Janas et al., are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Hubbard et al. do not explicitly teach the amount of the ceramic material. This deficiency is cured by the teachings of Draenert.

Draenert teach an implantation material comprises a polymeric base of an acrylate, a polymethacrylate, a copolymer of an acrylate and a methacrylate or a mixture thereof, and 5-35% by weight of resorbable tricalcium phosphate of a particle size of 50-300 μm, and an available pore volume of less than 0.1 ml/g (see abstract).

Draenert teach that among the special advantages of the implantation materials is the fact that the bond of the basic acrylate polymer is not negatively affected by the

addition of this invention, due to the relatively low amounts of tricalcium phosphate added (column 2, lines 54-58).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the amount of the ceramic material such as tricalcium phosphate because Draenert teach the incorporation of particles of tricalcium phosphate in amounts of **5-35%** of the composition used to make the implant material. The skilled artisan would have been motivated to add the ceramic material such as the tricalcium phosphate in amounts as recited because Draenert teach smaller amounts of the bond of the basic acrylate polymer is not negatively affected by the addition of this invention, due to the relatively low amounts of tricalcium phosphate added (column 2, lines 54-58). Additionally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Draenert, because both references teach similar biocompatible materials that can be used for implantation.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 38 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) in view of Janas et al. (US Patent No. 6451059) and Gertzman et al. (US Patent No. 7019192).

Applicant Claims

The claimed subject matters of instant claim 38 and 51 are set forth above. Instant claim 52 recites the implant according to claim 51 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of greater than one million daltons. Instant claim 53 recites the implant according to claim 51 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of from one million to five million daltons.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al., and Janas et al., are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Hubbard et al. teach both hyaluronic acid and hyaluronic acid and xanthan as polysaccharide gel types incorporated as a carrier, Hubbard et al. do not explicitly teach molecular weights of the hyaluronic acid. This deficiency is cured by the teachings of Gertzman et al.

Gertzman et al. teach a formable bone composition for application to a bone defect site to promote new bone growth at the site which comprises a new bone growth inducing compound of demineralized lyophilized allograft bone particles (see abstract). The particle size ranges from about 0.1 mm to about 1.0 cm and is mixed in a hydrogel carrier containing a sodium phosphate saline buffer, the hydrogel component of the carrier ranging from about 1.0 to 5.0% of the composition and a pH between 6.8 7.4 with one or more additives of a cellular material, growth factor, demineralized bone chips or mineralized bone chips (see abstract). The primary role of a carrier is to serve as a delivery vehicle (column 6, lines 45-46). **The carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such Sodium Hyaluronate (hyaluronic acid) 6.6 x 10^5- 2.6 x 10^6 Daltons and its derivatives** (column 7, lines 7-10).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the material of Hubbard et al. via the incorporation of hyaluronic acid based polysaccharides with molecular weights as specified, because Gertzman et al. teach the use of hyaluronic acid based polysaccharides with molecular weight as taught above for making materials for the purpose of bone growth. The skilled artisan would have been motivated to incorporate hyaluronic acid based polysaccharides with molecular weights as

specified because Gertzman et al. teach that such a carrier can serve as a delivery vehicle (column 6, lines 45-46). The carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such as Sodium Hyaluronate (hyaluronic acid) 6.6 x 10^5- 2.6 x 10^6 Daltons and its derivatives (column 7, lines 7-10). Additionally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Gertzman et al., because both references teach similar biocompatible materials that can be used for the growth of bone.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 55 -66 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) in view of Draenert (US Patent No. 4373217).

Applicant Claims

Applicants claim a resorbable implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension

in at least one vector fluid, wherein said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months, have a size of from 10 to 80 ~m, and are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%, said ceramic compound is tricalcium phosphate (13TCP), and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties. The dependent claims thereof recite sizes of microparticles, contents of fluids, durations of biological properties of the implant, amounts of vector fluid, and forms of implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Hubbard et al. do not explicitly teach the amount of the ceramic material (microparticles). This deficiency is cured by the teachings of Draenert.

Draenert teach an implantation material comprises a polymeric base of an acrylate, a polymethacrylate, a copolymer of an acrylate and a methacrylate or a mixture thereof, and 5-35% by weight of resorbable tricalcium phosphate of a particle size of 50-300 µm, and an available pore volume of less than 0.1 ml/g (see abstract).

Draenert teach that among the special advantages of the implantation materials is the fact that the bond of the basic acrylate polymer is not negatively affected by the addition of this invention, due to the relatively low amounts of tricalcium phosphate added (column 2, lines 54-58).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the amount of the ceramic material such as tricalcium phosphate because Draenert teach the incorporation of particles of tricalcium phosphate in amounts of **5-35%** of the composition used to make the implant material. The skilled artisan would have been motivated to add the ceramic material such as the tricalcium phosphate in amounts as recited because Draenert teach smaller amounts of the bond of the basic acrylate polymer is not negatively affected by the addition of this invention, due to the relatively low amounts of tricalcium phosphate added (column 2, lines 54-58). Additionally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Draenert, because both references teach similar biocompatible materials that can be used for implantation. With regard to the recitations of the duration at which the implant material would be biodegradable in instant claims 55 and 62-63 since the product taught by Hubbard et al. is substantially similar to the instantly claimed

product, the product of Hubbard et al. is necessarily expected to take similar durations to degrade under physiological conditions.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 55 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) in view of Gertzman et al. (US Patent No. 7019192).

Applicant Claims

The claimed subject matters of instant claims 55 and 66 are set forth above. Instant claim 67 recites the implant according to claim 66 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of greater than one million daltons. Instant claim 68 recites the implant according to claim 66 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of from one million to five million daltons.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Hubbard et al. teach both hyaluronic acid and hyaluronic acid and xanthan as polysaccharide gel types incorporated as a carrier, Hubbard et al. do not explicitly teach molecular weights of the hyaluronic acid. This deficiency is cured by the teachings of Gertzman et al.

Gertzman et al. teach a formable bone composition for application to a bone defect site to promote new bone growth at the site which comprises a new bone growth inducing compound of demineralized lyophilized allograft bone particles (see abstract). The particle size ranges from about 0.1 mm to about 1.0 cm and is mixed in a hydrogel carrier containing a sodium phosphate saline buffer, the hydrogel component of the carrier ranging from about 1.0 to 5.0% of the composition and a pH between 6.8 7.4 with one or more additives of a cellular material, growth factor, demineralized bone chips or mineralized bone chips (see abstract). The primary role of a carrier is to serve as a delivery vehicle (column 6, lines 45-46). **The carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such Sodium Hyaluronate (hyaluronic acid) 6.6 x 10^5- 2.6 x 10^6 Daltons and its derivatives** (column 7, lines 7-10).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the material of Hubbard et al. via the incorporation of hyaluronic acid based polysaccharides with molecular weights as specified, because Gertzman et al. teach the use of hyaluronic acid based polysaccharides with molecular weight as taught above

for making materials for the purpose of bone growth. The skilled artisan would have been motivated to incorporate hyaluronic acid based polysaccharides with molecular weights as specified because Gertzman et al. teach that such a carrier can serve as a delivery vehicle (column 6, lines 45-46). The carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such as Sodium Hyaluronate (hyaluronic acid) 6.6 x 10^5- 2.6 x 10^6 Daltons and its derivatives (column 7, lines 7-10). Additionally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Gertzman et al., because both references teach similar biocompatible materials that can be used for the growth of bone.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

Claims 38-69 are rejected. Claims 34 and 36-37 are withdrawn. Claims 1-33 and 35 are cancelled. Applicants newly added claims 38-69.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 7/24/10

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647